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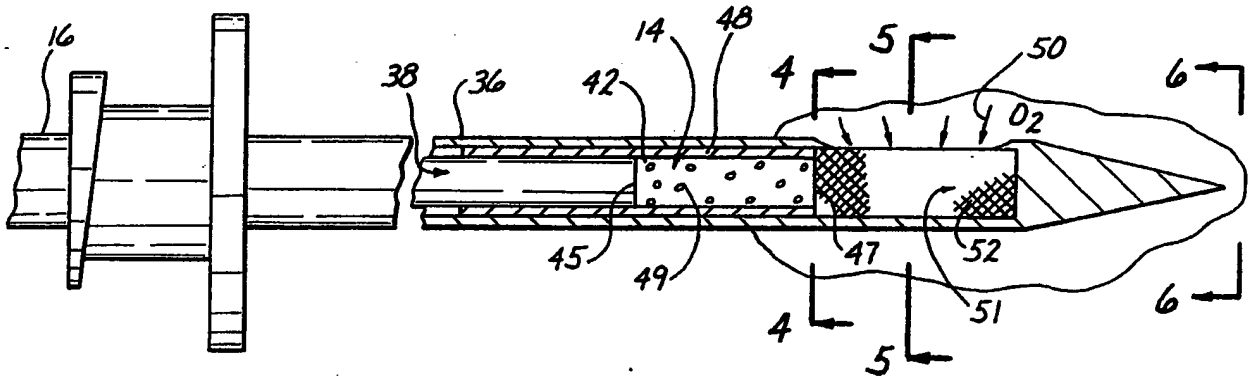

(57) Abstract

A probe (10) adapted for direct insertion into the tissue of a patient, includes a needle (21) having walls defining an interior lumen (38) and a closed tip with a generally conical configuration. At least one sensor (14) capable of measuring a particular physiological parameter is disposed in the lumen. At least one window (41) is formed in the needle wall (36) along a path between the tissue and the sensor. A filler material (52) disposed along the path inhibits the passage of air or blood while facilitating transmission of the particular physiological parameter of interest such as oxygen, carbon dioxide, pH, and pressure.

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DIRECT INSERTABLE TISSUE PROBE

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to sensors for measuring physiological parameters and more specifically to sensors for measuring blood gas concentrations, pressures, and other physiological parameters in the tissue of a patient.

Discussion of the Prior Art

Tissue probes are devices which are adapted to be inserted into the tissue of a patient to measure various physiological parameters such as oxygen concentration, carbon dioxide concentration, pH, and pressure. These sensors are typically carried by a probe which is disposed at the end of a long flexible catheter.

In order to introduce the flexible catheter into a relatively hard tissue mass, the prior art has relied upon a catheter introducer which is more commonly used to provide access for catheters and other instruments directly into the vessels of a patient. For this purpose the introducer includes a needle and an overlying sleeve or cannula which is carried by the needle. When used for accessing a tissue bed, the needle and sleeve are inserted into the tissue bed and the needle is removed leaving the sleeve in place with the cannula defining a channel into the tissue bed. The flexible catheter can then be

introduced through the cannula up to the point where the sensor contacts the tissue at the end of the sleeve. At this location the sensor can be activated to provide the measurements of interest.

The sensor of such a catheter might include the fiber optic probe disclosed and claimed in U. S. Patent Application Serial No. 100,100 filed on September 21, 1987. This probe includes a fiber optic probe connector for measuring physiological parameters such as the concentration of oxygen in tissue. The device includes an optical fiber and a sleeve connector including a sheath substrate which defines a sensor cavity and an annular recess for receiving the fiber core. The sheath comprises a gas permeable polymer material which permits the passage of oxygen ions into the region of the sensor.

A chemical indicator including an oxygen quenching fluorescent dye is disposed in the sensor region and interrogated by incident light from the fiber. The fluorescent dye includes a reversible chemical indicator having fluorophors which fluoresce in response to the incident light, with an intensity which is dependent upon the concentration of oxygen. The fluorescent return light is then measured to provide an indication of oxygen concentration.

U. S. Patent Application Serial No. 359,254 filed on September 31, 1989, discloses a fiber optic probe having a sensor including a core of fluorescent dye and a cladding which functions as a wave guide to maintain light within the core material. These patent applications are incorporated herein by reference for their disclosure of probes which might be useful as tissue sensors in accordance with the present invention.

It will be appreciated from the foregoing comments that the past procedures for inserting tissue sensors have involved many separate devices, and many steps in the procedures. This has made the process particularly complex and susceptible to both contamination and infection. Such procedures have been time consuming and have severely limited the surgeon's ability to quickly sample a variety of tissue sites.

While various needles have been available for introducing fluids directly into a tissue bed, these devices have not been configured to carry a sensor to a tissue site of interest. Furthermore, needles which are open on the end are totally inappropriate for tissue sensing as they tend to introduce blood and air into the region of the sensor. Other needles, such as that disclosed by Wang in U. S. Patent No. 4,702,260, have been provided with lateral openings in order to pass tissue samples into a hollow sampling needle. Any such tissue samples would interfere with the reading of a sensor. Other needles providing lateral openings are disclosed in the following patents:

Inventor	U. S. Patent No.
Magasi	4,826,492
Coombs	4,808,157
Nuesch	703,296
Friedell	3,841,307
Overland	4,496,353

As a matter of background, these patents are all incorporated herein by reference. Notwithstanding the scope of this prior art, the complex apparatus and methods associated with the insertion of sensors into tissue, have remained a problem.

SUMMARY OF THE INVENTION

These problems are overcome in accordance with the present invention which provides for a sensor probe which is directly insertable into the tissue of a patient. A needle is provided with a closed end having a conical surface which facilitates piercing without cutting. The needle has walls which define an interior lumen that extends along the axis of the needle. Portions of the walls define at least one window which provides access between regions exterior of the needle and the interior lumen. A sensor, such as that previously referenced, is disposed in the lumen and positioned to receive input from the physiological parameter of interest. For example, in one embodiment where oxygen concentration in the tissue is of interest, the sensor is disposed to receive oxygen molecules through the window and to provide a measurement of the concentration of those molecules within the tissue.

Since extraneous light may interfere with this measurement, a particular embodiment may include an opaque sleeve or window pane which is permeable to the physiological parameter of interest. As an alternative, the sensor may be recessed to form a cavity between the sensor and the distal end of the window. This cavity can be filled with an opaque, oxygen permeable material to facilitate the measurement without interference from extraneous light.

In one aspect, the invention includes a probe for directly inserting a sensor into the tissue of a patient. The probe includes a needle having a wall defining a lumen which extends between distal and proximal ends along an elongate axis of the needle. Means is included in the needle for defining a point along the axis at the distal

end of the needle, while other portions of the needle define at least one window extending through the wall. This window provides access for an analyte or other physiological parameter of interest to pass from the tissue outside the needle to the lumen inside the needle. The sensor is disposed in the lumen and provided with characteristics which are variable in accordance with a particular property of the analyte. Means responsive to these characteristics of the sensor determine the particular property of the analyte in the tissue.

In another aspect to the invention, means is provided for closing the lumen of the needle at the distal end of the needle. This closing means has the configuration of a cone which in a preferred embodiment is a right cone.

These and other features and advantages of the invention will become more apparent with a description of preferred embodiments and reference to the associated drawings.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a probe of the present invention directly inserted into the tissue of an arm of a patient;

Fig. 2 is a perspective view of the tissue probe illustrated in Fig. 1, the probe including a conical point and a lateral window;

Fig. 3 is an axial cross-section view of the probe taken along lines 3-3 of Fig. 2;

Fig. 4 is a radial cross-section view of the probe taken along lines 4-4 of Fig. 3;

Fig. 5 is a radial cross-section view of the probe taken along lines 5-5 of Fig. 3;

Fig. 6 is an end view taken along lines 6-6 of Fig 3;

Fig. 7 is an axial cross-section view of a further embodiment of the probe of the present invention;

Fig. 8 is an axial cross-section view of an additional embodiment of the probe of the present invention;

Fig. 9 is an axial cross-section view of further embodiment of the probe illustrating a fenestration of windows in the walls of the probe;

Fig. 10 is a side elevation view illustrating a preferred method for using a single window embodiment of the probe;

Fig. 11 is an axial cross-section view of a probe of the present invention including a pH sensor;

Fig. 12 is an axial cross-section view of a probe of the present invention including a pressure sensor; and

Fig. 13 is a side elevation view of a further embodiment of the probe of the present invention including more than one sensor;

Fig. 14 is a radial cross-section view of the probe taken along lines 14 - 14 of Fig. 13; and

Fig. 15 is a radial cross-section view of the probe taken along lines 15 - 15 of Fig. 13.

DESCRIPTION OF PREFERRED EMBODIMENTS

A probe is illustrated in Figure 1 and designated generally by the reference numeral 10. The probe 10 is adapted for direct insertion into a tissue bed 12, such as that present in an arm 13 of a patient.

A primary purpose of the probe 10 is to carry a sensor 14, best shown in Figure 3, into the tissue bed 13. This sensor can be of several types which are adapted to measure a physiological parameter such as blood pressure or the concentration of some analyte, such as a blood gas. The sensor 14 is coupled through a conductor 16 to a signal processor 18 which provides the information of interest.

By way of example, the sensor 14 may be an oxygen sensor for measuring the partial pressure of oxygen in the tissue bed. In such a case, the cable 16 includes optical fibers which illuminate and interrogate the sensor 14 in the manner disclosed in the afore mentioned U. S. Patent Application Serial No. 100,100. In this case, the processor 18 include a fiber optic detector and various filters for measuring the fluorescence of dye in the sensor 14.

Referring now to Figure 2, the probe 10 in the illustrated embodiment includes a needle 21 which extends along an elongate axis 22 from a proximal end 23 to a distal end 25. At the distal end 25, the needle 21 is provided with a piercing structure shown generally at 27. This structure 27 includes a conical outer surface 29 and

a point 32 which may be disposed along the axis 22. At the proximal end 23, the needle 21 will typically be provided with some gripping means such as a handle 34.

The handle 34 is shown in axial cross-section in Figure 3 where the needle 21 is illustrated to include a wall 36 which define a central lumen 38 that extends proximally through the handle 34.

Portions of the wall 36 define at least one window 41 near the distal end 25 of the needle 21. Although this window 41 can be defined in the conical surface 29 of the piercing mechanism 27, it may be desirable that it face generally laterally of the needle 21 as illustrated in Figure 3.

The sensor 14 is disposed in the lumen 38 of the needle 21 in proximity to the window 41. In a preferred embodiment, the sensor 14 includes a dye matrix 42 having a lateral surface 43, a proximal end surface 45, and a distal end surface 47. A connector sleeve 48 surrounds the matrix 42 and the optical fiber which forms the cable 16. Thus the sleeve 48 forms a connector which maintains the cable 16 and the proximal end surface 45 of the matrix 42 in abutting relationship. The lateral surface 43 of the dye matrix 42 may contact the inner surface of the sleeve 48 while the outer surface of the sleeve 48 contacts the wall 36 of the needle 21.

It is particularly desirable that the piercing mechanism 27 be closed in order to inhibit the passage of blood and air into the lumen 38 of the needle 21. If the mechanism 27 is closed, then the only path which oxygen can follow in passing from the tissue bed 12 to the sensor 14 is through the window 41.

In a particular embodiment, the sensor 14 may be disposed directly beneath the window 41, as illustrated in the embodiment of Figure 7; however, in some cases this disposition will make the sensor 14 too susceptible to extraneous light. For this reason, the sensor 14 in the Figure 3 embodiment is disposed with the distal surface 47 in juxtaposition to the most proximal edge of the window 41. In a preferred embodiment, the surface 47 extends radially of the needle 21 in a plane which includes this proximal edge of the window 41. With this disposition, the lateral surface 43 of the sensor 14 is hidden from the window 41 and only the distal surface 47 is available to be contacted by the oxygen molecules, such as those represented by the arrows 50.

If the sensor 14 is recessed, as illustrated in Figure 3, the lumen 38 forms a cavity 51 beneath the window 41 between the sensor 14 and the distal end 25 of the needle 21. It is desirable that this cavity 51 be filled to keep any gases, blood or other fluid from collecting in the path of the oxygen molecules 50. In the illustrated embodiment, this cavity 51 between the sensor 14 and the distal end 25 of the needle 21, is filled with a plug 52.

In order to insure that this plug 52 does not interfere with the measurements of the sensor 14, the material of the plug 52 must be permeable to, or otherwise transmissive of, the oxygen molecules 50. Thus in a particular embodiment, the plug 52 not only provides means for filling the cavity 51 but also means for facilitating the transmission of the analyte, such as oxygen, to the sensor 14. In the case of an oxygen sensor, the plug 52 can be formed from silicone.

Even though the sensor 14 can be recessed from the window 41, extraneous light may still create sufficient error in the measurement to be of concern. In this case, the plug can also be provided with an opacifying agent which inhibits the passage of light through the window 41. In general, the plug 52 can be formed from any material which is capable of filling the cavity 51, which is permeable to the physiological parameter of interest, and/or which is opaque to extraneous light. In a preferred embodiment, including an oxygen sensor, the plug 52 is formed from silicone impregnated with an opacifying agent such as ferrous oxide.

In the embodiment of Figure 7, the walls 36 which form the needle 21 also form the piercing mechanism 27. In this case, the cavity 51 extends from a location proximal of the window 41 into the mechanism 27 at the distal end 25 of the needle 21. The embodiment of Figure 7 also illustrates that the entire cavity 51 can be filled with the dye matrix material of the sensor 14. In such an embodiment only the proximal regions of the sensor 14 may enter the measurement calculations; nevertheless, the remainder of the sensor material provides oxygen permeable means for filling the cavity 51.

Figure 7 also discloses an alternative structure for the piercing mechanism 27. Although the piercing mechanism 27 preferably has the configuration of a cone, this structure may not necessarily be a right cone. In Figure 7, the piercing mechanism 27 is conical, but the point 32 does not lie along the axis 22.

In a further embodiment of the invention, the sensor 14 can be disposed beneath the window 41 as illustrated in Figure 8. In this case, the sleeve 48 can be provided with

an opacifying agent, such as ferrous oxide, in order to inhibit the effects of extraneous light on the measurement. Thus the sleeve 48 in this embodiment provides means for inhibiting the effects of extraneous light while remaining permeable to the analyte of interest. Alternatively, the sleeve 48 may fill the window 41 as an extension of the wall 41. In such an embodiment, the sleeve 48 appears as a window pane.

It may also be advantageous to extend the sleeve 48 beyond the distal end surface 47 of the die matrix 42. This region can be advantageously filled by the plug 52 which in this embodiment can be formed from the same material as that of the sleeve 48.

In general, the size of the window 41 is to be maximized in order to provide optimal access between the sensor 14 and the tissue bed 12. However, there are certain structural limitations which need to be considered. If the needle 21 is formed of stainless steel, it is generally felt that the circumferential width of the window 41 should be limited to a range of 40% to 70% of the circumference of the wall 36. Generally, the lower the number of windows, the lower the percentage in this range. For example, in one embodiment which includes a single window, the circumferential width of that window is only 40% of the entire circumference of the wall 36. However, in an embodiment including four or more windows which are equally spaced around the circumference of the needle 21, the combined circumferential width of the windows may be as high as 70% of the circumference of the needle 21. The intention is to provide sufficient column strength that the needle will not bend when subjected to the piercing forces.

The selection of a window pattern may also be dependent upon the presence of extraneous light. In the embodiment of Figure 3 which includes the single window 41, the probe 10 can be rotated to face away from any extraneous light fixture such as that designated by the reference numeral 60 in Figure 10.

The preferred axial length for the window 41 is dependent on the diameter of the sensor 14, which is generally equivalent to the inside diameter of the needle 21. In most embodiments, the window 41 will have an axial length between 0.5 and 14 times the diameter of the sensor 14. The best results seem to occur at the lower end of this range where the ratio between window length and sensor diameter is between one and four. In a preferred embodiment, the sensor 14 has a diameter of .013 inches and the axial length of the window 41 is approximately .039 inches.

Although the invention has been described and illustrated with particular reference to a sensor 14 which measures the concentration of oxygen in tissue, it will be apparent that other sensors can equally benefit from the concepts of the present invention. These sensors might include similar fluorescent sensors which measure the concentration of other gasses such as carbon dioxide.

The sensors may also include absorption sensors such as the pH sensor 69 illustrated in the embodiment of Figure 11. In this figure, similar structural elements are designated by the same reference numerals followed by a lower case "a". Thus the pH needle is designated by the numeral 21a.

In the embodiment of Figure 11, the sensor 69 includes a fiber optic cable 16a which conveys incident light to an operative element 70 which has characteristics for changing color in accordance with the concentration of hydrogen ions 50a introduced to the element 70. This color change in the element 70 is detected by light which is reflected by a mirror 72 back along the fiber 16a.

The operative element 70 in a preferred embodiment comprises a sheet of cellophane which is disposed in a radial plane in contact with the fiber 16a. The cellophane of the element 70 is impregnated with a dye which changes colors in response to the presence of hydrogen ions 50a.

In accordance with the present invention, these hydrogen ions 50a pass through the window 41a and through a filler material or plug 52a which is permeable to the hydrogen ions. These ions pass through axial passages 74 in the mirror 72 in order to reach the operative element 70.

In a preferred embodiment, the mirror 72 is formed from glass which is provided with a coating of gold on its proximate surface to provide the reflective characteristics. A plurality of the passages 74 extend axially from the plug 52a through the glass substrate and gold coating of the mirror 72.

The sensor 69 can be recessed from the window 41a as illustrated in Figure 11 or disposed beneath the window 41a in the manner illustrated in Figure 8.

The material forming the plug 52a preferably has characteristics for filling the cavity 51a, but also properties which are permeable to the ion of interest. In

the case of the pH sensor 14a, the plug 52a is formed from Hydrogel which is permeable to hydrogen ions.

Another type of sensor which might be used with the present invention could include a pressure sensor 79 such as that disclosed by Saaski in U. S. Patent No. 4,945,230. This embodiment of the invention is illustrated in Figure 12 where like structural elements are referenced with the same numerals followed by a lower case "b". In this case, the sensor 79 includes a substrate 80 which forms a cavity 82 with a cover 84.

The cavity 82 is formed with two radial surfaces which are of particular interest. The first is a distal surface 86 of the substrate 80; the second is a proximal surface 88 of the cover 84. Light from the fiber 16 which impinges on these two surfaces 86, 88 is spectrally modulated in accordance with the distance separating the surfaces 86, 88. In response to pressure, this separation distance varies an amount which is detectable to determine the magnitude of the pressure on the cover 84.

In accordance with the present invention, the pressure sensor 79 can be disposed relative to the window 41b so that pressures in the surrounding tissue are transmitted to the cover 84. In this embodiment, the plug 52b must be formed with a material which has characteristics for transmitting the pressure from the window 41b to the cover 84. In a preferred embodiment, the plug 52b is formed from Hydrogel or a polymer having a low cured viscosity such as silicone. A silicone of particular interest is that manufactured by Dow Chemical and marketed under its trademark Visolox®.

A further embodiment of the invention includes multiple sensors in a single probe. This embodiment, illustrated in Figure 13, includes structures similar to those previously discussed which are designated with the same reference numerals followed by the lower case letter "c".

In the case of the probe 10c, a single needle 21c includes a single lumen 38c. However, multiple sensors 90, 92 and 94 are disposed in the lumen 38c as best illustrated in Figure 14. Each of these sensors 90 - 94 can include its respective fiber optic cable 16c and an appropriate die matrix or other operative element having characteristics responsive to the analytes or physical parameters of interest. Each of the sensors 90 - 94 may also have an associated window 41c which is appropriately positioned and sized for the associated sensor 90 - 94. The single cavity 51c in this embodiment can be filled with a single material which is permeable to all of the analytes or physical properties of interest. Alternatively, the plug 52c can be provided with discrete segments 96, 98, 100 which are respectively permeable to the analyte being sensed by the associated sensor 90 - 94.

Thus the present invention provides for a probe which is directly insertable into the tissue of a patient. The probe can be provided with a conical tip and lateral windows which permit the analyte or other physiological parameter of interest to be sensed from inside the needle. The sensor can be disposed directly beneath the window to sense the analyte concentration. If extraneous light is objectionable, the sensor can be recessed from the window and a permeable, opaque plug can be provided to fill the resulting cavity. Alternatively, a permeable, opaque

material can be disposed in the path between the sensor and the window.

With all of the possible combinations of these variables, the scope of the invention should not be ascertained with reference merely to the disclosed embodiments, but should be determined only with reference to the following claims.

CLAIMS

1. A probe for directly inserting an analyte sensor into the tissue of a patient to measure a phyisiological parameter in the tissue, comprising:

a needle having a wall defining a lumen which extends along an elongate axis between a distal end and a proximal end of the needle;

means included in the needle for defining a point along the axis at the distal end of the needle;

portions of the needle defining at least one window extending through the wall of the needle, the window providing access for the parameter from the tissue outside the needle into the lumen inside the needle;

the sensor being disposed in the lumen and having characteristics variable in accordance with a particular property of the parameter; and

means responsive to the characteristics of the sensor for determining the particular property of the parameter in the tissue.

2. The probe recited in Claim 1 wherein:

the sensor is disposed proximally of the window;

portions of the wall define a cavity coextensive with the lumen between the sensor and the distal end of the needle; and

means disposed in the cavity for inhibiting the passage of liquids and gases not in solution between the tissue and the sensor, the inhibiting means being transmissive of the parameter.

3. The probe recited in Claim 1 wherein the physiological parameter includes one of ions and molecules.

4. The probe recited in Claim 3 wherein the physiologiical parameter is oxygen.

5. The probe recited in Claim 1 wherein the particular property of the physiological parameter is the concentration of the analyte in the tissue.

6. The probe recited in Claim 2 wherein the inhibiting means includes an opacifying agent having characteristics for inhibiting the passage of extraneous light through the window.

7. The probe recited in Claim 3 wherein the physiological parameter is hydrogen.

8. The probe recited in Claim 1 wherein the portions define a fenestration of windows equally spaced around the circumference of the needle.

9. The probe recited in Claim 2 wherein the inhibiting means comprises a sleeve disposed over the sensor and covering the window, the sleeve being transmissivie of the parameter and opaque to light.

10. The probe recited in Claim 2 wherein:

the sensor includes a particular material having the variable characteristic in response to the analyte; and

the inhibiting means includes an extension of the particular material.

11. A probe for directly inserting an analyte sensor into the tissue of a patient, comprising:

a needle having a wall defining a lumen which extends along an elongate axis between a distal end and a proximal end of the needle;

means for closing the lumen of the needle at the distal end of the needle;

portions of the needle defining at least one window extending through the wall of the needle, the window providing access for the analyte to pass from the tissue outside the needle into the lumen inside the needle;

the sensor being disposed in the lumen and having characteristics variable in accordance with a particular property of the analyte; and

means responsive to the characteristics of the sensor for determining the particular property of the analyte in the tissue.

12. The probe recited in Claim 11 wherein the closing means is configured to define a point at the distal end of the needle.

13. The probe recited in Claim 12 wherein the closing means has the configuration of a cone.

14. The probe recited in Claim 13 wherein the cone is a right cone and the point is disposed along the axis of the needle.

15. The probe recited in Claim 11 wherein:

the sensor is disposed proximally of the window;

portions of the wall define a cavity coextensive with the lumen between the sensor and the distal end of the needle; and

means disposed in the cavity for inhibiting passage of liquids between the window and the sensor, the inhibiting means being permeable to the analyte.

16. The probe recited in Claim 11 wherein the window has a proximal end and a distal end and the sensor has a surface which is disposed generally radially of the lumen in juxtaposition to the proximal end of the window.

17. A probe for directly inserting a sensor into the tissue of a patient, the sensor having properties for measuring a particular physiological parameter, comprising:

a needle having a distal end and a proximal end and being adapted for operative disposition in the tissue of the patient;

a wall included in the needle which defines a lumen extending through the proximal end of the needle to the distal end of the needle;

the sensor being disposed in the lumen;

portions of the wall disposed relative to the sensor and defining at least one window along a path extending through the wall between the tissue of the patient and the sensor in the lumen; and

means disposed along the path for creating a barrier to fluids, the barrier being transmissive of the physiological parameter.

18. The probe recited in Claim 17 wherein the barrier is a sleeve disposed circumferentially of the sensor between the tissue and the sensor.

19. The probe recited in Claim 17 wherein the barrier comprises a pane disposed in the window and supported by the wall portions.

20. The probe recited in Claim 17 wherein the barrier is opaque to light.

21. The probe recited in Claim 17 wherein the sensor is an analyte sensor and the particular parameter is an analyte.

22. The probe recited in Claim 17 wherein the sensor is a pressure sensor and the particular parameter is fluid pressure.

23. A probe for directly inserting a plurality of sensors into the tissue of a patient, the sensors having individual properties for measuring a different physiological parameter, comprising:

a needle having a distal end and a proximal end and being adapted for operative disposition in the tissue of the patient;

a wall included in the needle and at least partially defining at least one lumen extending through the proximal end of the needle to the distal end of the needle;

the sensors being disposed in the at least one lumen; and

portions of the wall defining at least one window along a path extending between in the tissue of the patient and the sensors in the lumen.

24. The probe recited in Claim 23 further comprising means disposed along the path for creating a barrier to fluids, the barrier being transmissive of at least one of the physiological parameters.

25. The probe recited in Claim 23 wherein:

the wall portions define at least two windows each disposed along an associated path between the tissue and an associated one of the sensors; and

the creating means including a barrier disposed along each of the paths, each of the barriers having properties transmissive of an associated one of the physiological parameters.

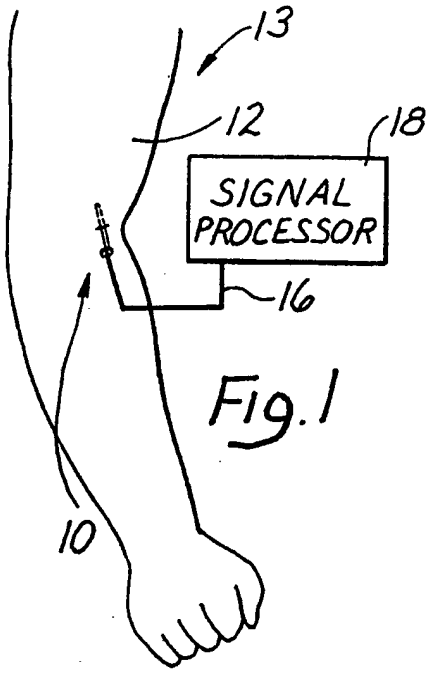

Fig. 1

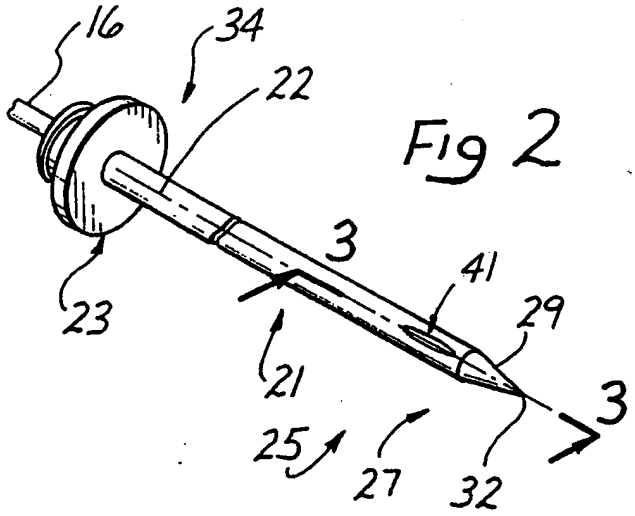

Fig 2

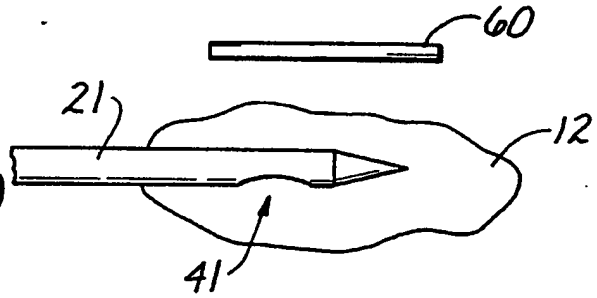

Fig. 10

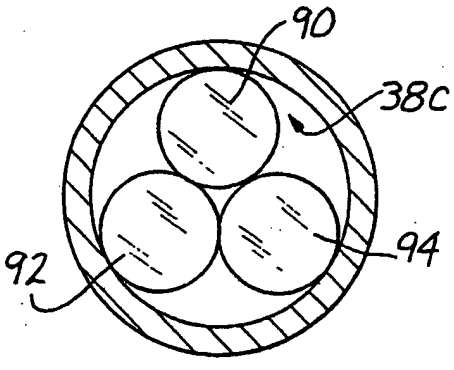

Fig. 14

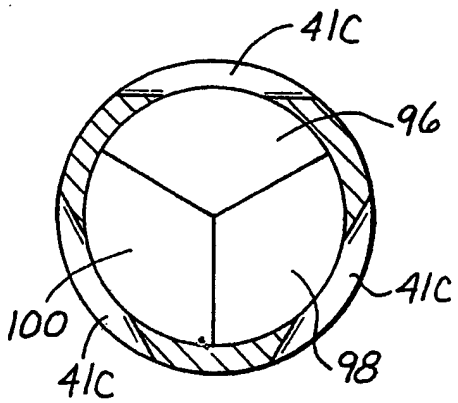

Fig. 15

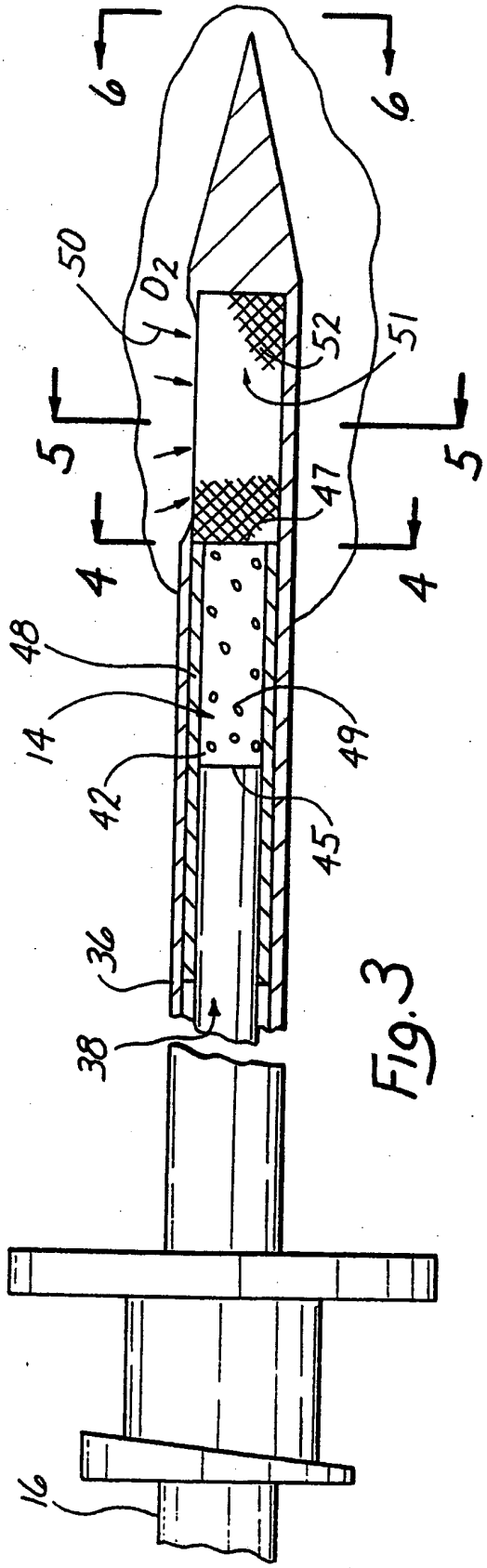

Fig. 3

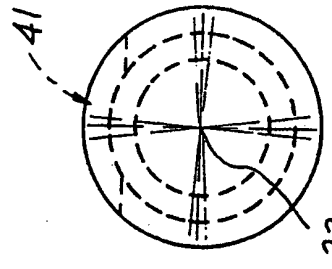

Fig. 6

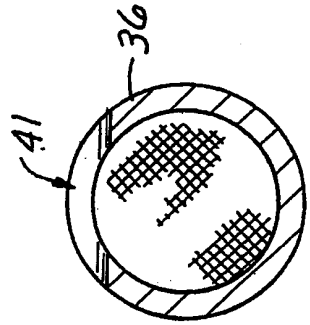

Fig. 5

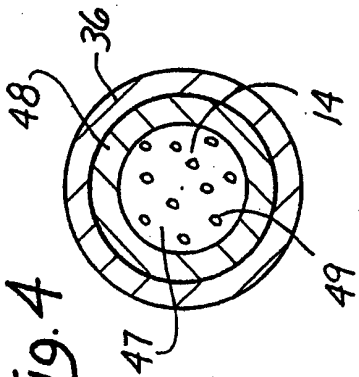

Fig. 4

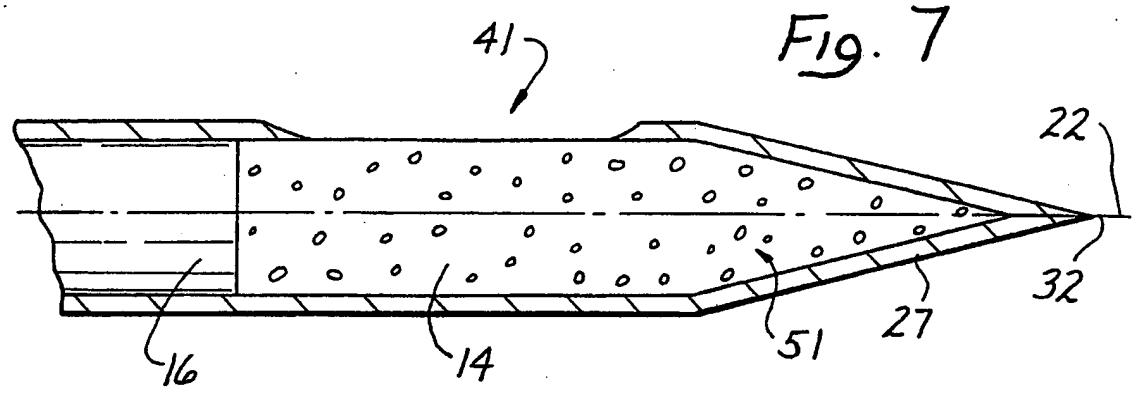

Fig. 7

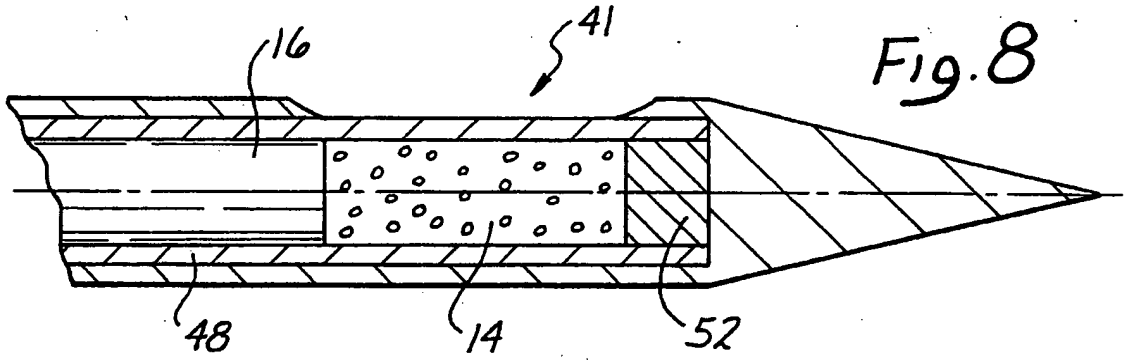

Fig. 8

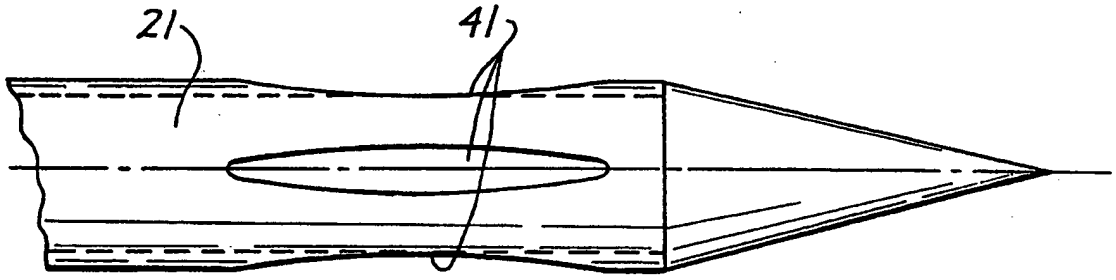

Fig. 9

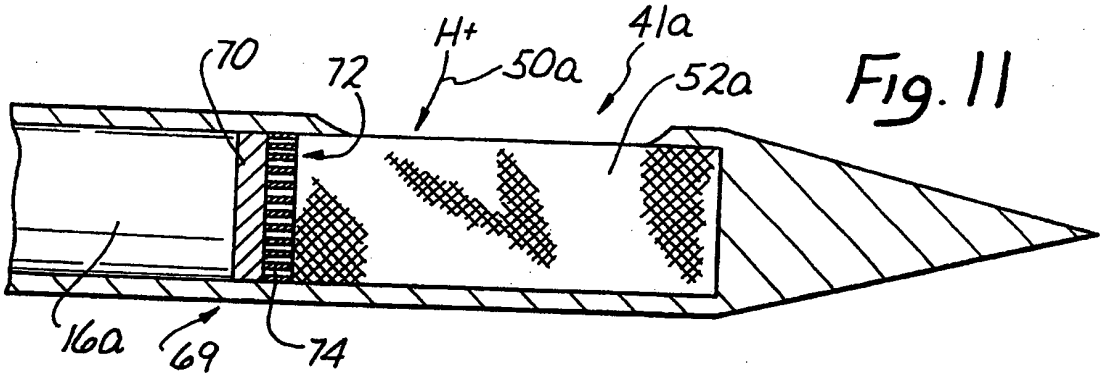

Fig. 11

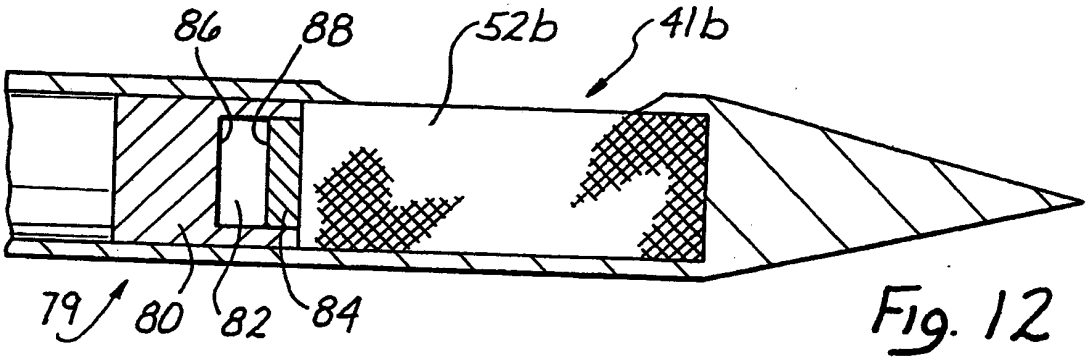

Fig. 12

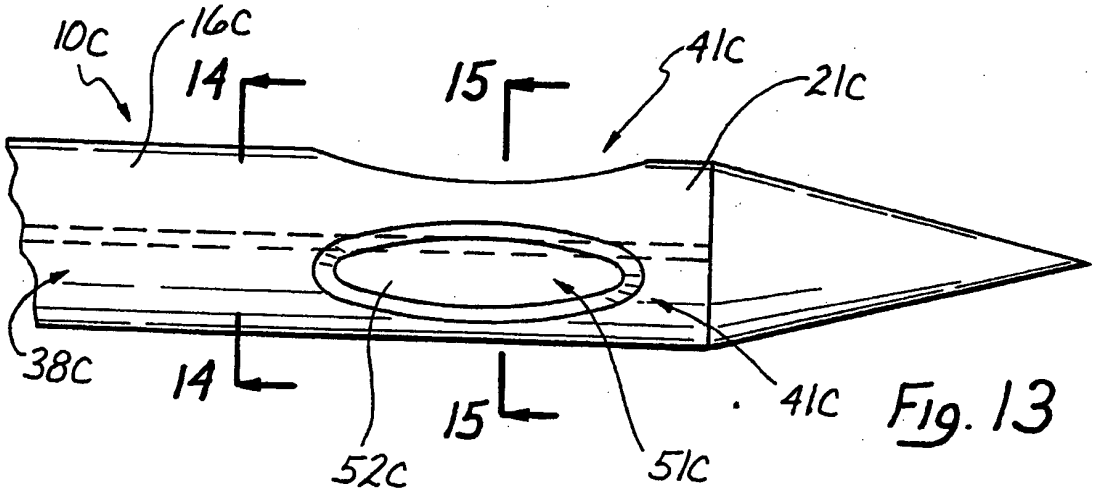

Fig. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/03620

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 5/00
US CL :128/632, 635, 637; 356/39; 606/185
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/632,633,634,635,636,637,754;606/185;604/264,272;356/39.40,41

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	EP, A, 0,320,109 (Wickham) 14 June 1989, See entire document.	1-3,5-6,9-21 and 23-24 4,7-8,25
Y,P	US, A, 5,020,537 (Gunther) 04 June 1991, See entire document.	8,25
Y	US, A, 4,671,288 (Gough) 09 June 1987, See entire document.	4,7
Y	US, A, 4,809,704 (Sogawa et al.) 07 March 1989, See entire document.	22
A,P	US, A, 5,063,930 (Nucci) 12 November 1991, See entire document.	1-25
A,P	US, A, 5,054,882 (Riccitelli et al.) 08 October 1991, See entire document.	1-25
A	US, A, 5,005,576 (Gunther) 09 April 1991, See entire document.	1-25
A	US, A, 4,478,222 (Koning et al.) 23 October 1984, See entire document.	1-25
A	US, A, 4,474,183 (Yano et al.) 02 October 1984, See entire document.	1-25

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)		
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed	"&"	document member of the same patent family

Date of the actual completion of the international search 05 OCTOBER 1992	Date of mailing of the international search report 14 OCT 1992
Name and mailing address of the ISA/ Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer KRISTA PFAFFLE Telephone No. (703) 308-0858

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/03620

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,432,366 (Margules) 21 February 1984, See entire document.	1-25
A	EP, A, 0,073,558 (Goldstein) 09 March 1983, See entire document.	1-25